

REMARKS

Claims 1, 7-12, 15, 16, 21-22 and 25-29 are pending in the present application. Claims 1, 16, 26, and 28 are amended and claims 2-6, 13-14, 17-20, 23 and 24 have been cancelled without prejudice to or disclaimer of the subject matter contained therein.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Background

As described in WO 99/23150, there are problems associated with the addition of anti-microbials to cyanoacrylate monomers:

A problem has arisen in the use of these prepolymer cyanoacrylate ester compositions. Particularly, when some antimicrobial agents are added to the composition, it has been found that premature polymerization or inhibited polymerization occurs. For instance, as disclosed in U.S. Serial No. 08/912,681 filed August 18, 1997 [now U.S. Patent No. 6086906], some antimicrobial agents were found not to be compatible with the polymerizable cyanoacrylate monomer compositions, e.g. tetracycline hydrochloride. First, some antimicrobial agents were not soluble or dispersible in the cyanoacrylate monomer composition at the concentrations necessary to effect antimicrobial properties. Second, some antimicrobial agents employed caused premature polymerization of the cyanoacrylate monomer compositions. Third, some antimicrobial agents employed prevented *in situ* polymerization for the cyanoacrylate monomer composition when applied to the skin, i.e., the composition did not cure. For example, it was found that elemental iodine (I₂) was only partially soluble in the polymerizable cyanoacrylate composition and prevented polymerization. Finally, some antimicrobial agents were not compatible with the intended use of the polymeric film because they inhibit formation of a flexible, durable film. Other antimicrobials caused premature polymerization, e.g., tetracycline hydrochloride caused polymerization within 24 hours of addition.

Because of these disparate properties, many conventional antimicrobial agents were found to be unsuitable for use in polymerizable cyanoacrylate compositions.

See Page 4, WO 99/23150. The presently claimed monomeric adhesive composition includes a polymerizable monomer and specific antimicrobial agents that ameliorate the foregoing issues in combining such ingredients.

Double Patenting Rejections

Claims 1-29 are rejected for nonstatutory obviousness-type double patenting over all of the claims of U.S. Patent Nos. 6,579,469 (particularly claim 1), 6,585,967 (particularly claim 11), 6,767,552 (particularly claim 15), 6,602,496 (particularly claim 15), and 6,942,875 (particularly claim 14) (Paragraph No. 3 of the Official Action). This rejection is obviated by amendment to the claims. In particular, none of the currently claimed anti-microbial agents are recited in any of the claims of the foregoing patents. Moreover, it would not have been obvious to select the currently claimed anti-microbial agents in view of the recognized problems associated with the addition of antimicrobials to cyanoacrylate monomers. Accordingly, it respectfully requested that the Examiner withdraw this rejection.

Claims 1-29 are rejected under nonstatutory obviousness-type double patenting as being unpatentable over any of U.S. Patent Nos. 5,981,621 (particularly claim 9), 6,143,352 (particularly claim 13), 6,306,243 (particularly claim 16), 6,310,166 (particularly claim 2), 6,352,704 (particularly claim 2), 6,455,064 (particularly claim 11), 6,512,023 (particularly claim 2), 6,605,667 (particularly claim 2), and 6,746,667 (particularly claim 2) in view of WO 97/32613 [*not commonly owned or under an obligation of assignment to Applicant*] or U.S. Patent No. 5,800,803 [*not commonly owned or under an obligation of assignment to Applicant*] (Paragraph No. 4 of the Official Action). The rejection is traversed for the following reasons.

This is an improper obviousness-type double patenting rejection because it is not focused on the claims of prior issued patent to Applicants and relies upon the further combination of two prior art patents that are not commonly owned or under an obligation of assignment to Applicant. In *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 68 U.S.P.Q.2d 1373, n. 1 (Fed. Cir. 2003), the Federal Circuit explained an important distinction between obviousness under 35 U.S.C. §103 and nonstatutory double patenting:

The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to the claims in a later patent or application...

As explained in M.P.E.P. §804, the first step of analysis in obvious type double patenting requires determining *the scope and content of a patent claim relative to a claim in the application* at issue. This is different than the obviousness standard under 35 U.S.C. § 103 which requires determination of the scope and content of the prior art relative to a claim in the application. Indeed, this section of the M.P.E.P. makes it clear that even the disclosure of the patent underlying the double patenting

rejection is not considered prior art for the purposes of an obviousness type double patenting rejection. Accordingly, the rejection should be withdrawn.¹

Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/355,294 and claims 1-41 of copending Application No. 10/429,050 (paragraph 5 of the Official Action). This rejection is moot with respect to Application No. 10/355,294 because the application is now abandoned. Upon an indication of allowability of the present claims, an appropriate terminal disclaimer will be filed with respect to copending Application No. 10/429,050.

Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 09/964,415 in view of WO 97/32613 [*not commonly owned or under an obligation of assignment to Applicant*] or U.S. Patent No. 5,800,803 [*not commonly owned or under an obligation of assignment to Applicant*] (Paragraph No. 6 of the Official Action). This rejection is improper for the same reasons as the rejection of Paragraph No. 4 of the Official Action and should be withdrawn.

In view of the above, all of the double patenting rejections should be withdrawn.

¹ Even if the rejection were somehow proper, it should be withdrawn because the prior patents owned by assignee do not disclose or suggest the claimed anti-microbial agents. The Official Action relies on prior art that one of ordinary skill in the art would not have combined because of the known problems associated with mixing anti-microbial agents with cyanoacrylate monomers.

Rejections Under 35 U.S.C. §112

Claims 1-29 are rejected under 35 U.S.C. §112, first paragraph (Paragraph No. 8 of the Official Action). The identity of the monomer and the anti-microbial agents are now specified in the claims by amendment. Accordingly, the rejection should be withdrawn.

Claims 7, 12, and 21 are also rejected under 35 U.S.C. §112, first paragraph (Paragraph No. 10 of the Official Action) for the use of the term “substantially”. The term “substantially” is understood by those of ordinary skill in the art reading each claim. With respect to claims 7 and 21, the term “substantially” is used to indicate that no significant amount of monomer has begun to polymerize for at least five minutes after forming the composition. In claim 12 the term indicates that presence of the antimicrobial does not materially impact the rate of polymerization of the composition. Accordingly, these terms are sufficiently clear and the rejection is respectfully requested withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1-4, 7-14, 16-19, 21-24, and 28-29 are rejected under 35 U.S.C. § 102(b) over WO 99/23150 (WO ‘150 Publication) (Paragraph No. 12 of the Official Action). The WO ‘150 Publication does not anticipate the claims because it is missing a cyanoacrylate monomer in combination with an antimicrobial agent. The WO ‘150 publication recognizes the known problems resulting from the mixing of cyanoacrylate monomers with anti-microbial agents as discussed in the Background section set forth above and teaches away from the presently claimed combination. The solution suggested in the WO ‘150 Publication is the use of a cyanoacrylate polymer in combination with a biocompatible solvent and an anti-microbial agent. The polymer is dissolved in the solvent and mixed with an anti-microbial agent. In contrast, the present claims are directed to the use of a monomer in combination with an anti-microbial agent. The presently claimed combinations avoid the known problems discussed in the WO ‘150 Publication whereas the WO’ 150 Publication does not suggest a way to avoid these issues with monomer. Instead, it suggests the use of a dissolved cyanoacrylate polymer. Accordingly, the rejection should be withdrawn.

Claims 1-5, 7-12, 16-22, and 28-29 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,281,265 (Paragraph No. 13 of the Official Action). This reference also does not anticipate the claimed combination because it does not disclose the use of cyanoacrylate monomer. Moreover, the use of the claimed anti-microbial agents would not have been suggested because of the problems discussed above with respect to the use of cyanoacrylate monomer. Accordingly, the rejection should be withdrawn.

Claims 1, 7-16, and 21-29 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,310,166 (Paragraph No. 14 of the Official Action). This patent also fails to anticipate the presently

claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 7-16, and 21-29 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,352,704 (Paragraph No. 15 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1-4, 7-12, 16-19, 21-22 and 28-29 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,455,033 (Paragraph No. 16 of the Official Action). This patent also does not anticipate the claimed combination because it is directed to preparation of artificial nails. In contrast, the claimed combination is a monomeric adhesive composition. This rejection should also be withdrawn.

Claims 1-4, 7-19, 21-26, 28 and 29 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,579,469 (Paragraph No. 17 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 2, 7-17 and 21-29 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,585,967 (Paragraph No. 18 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 2, 7-17 and 21-29 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,602,496 (Paragraph No. 19 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 2, 7-14, 16, 17, 21-24 and 28-29 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,767,552 (Paragraph No. 20 of the Official Action). This rejection is improper because U.S. Patent No. 6,767,552 is not a patent to "another". Both the present application and the '552 patent name Upvan Narang as the sole inventor and are commonly assigned to Closure Medical. Accordingly, it is respectfully requested that the Examiner withdraw this rejection.

Claims 1, 2, 7-14, 16, 17, 21-24 and 28-29 are rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,942,875 (Paragraph No. 21 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 2, 7-17, and 21-29 are rejected under 35 U.S.C. § 102(e) over U.S. Published Application No. 2004/0223946 (Paragraph No. 22 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Claims 1, 2, 7-14, 16, 17, 21-24, 28, and 29 are rejected under 35 U.S.C. § 102(e) over U.S. Published Application No. 2004/0151688 (Paragraph No. 23 of the Official Action). This patent also fails to anticipate the presently claimed combination because it does not disclose any of the claimed anti-microbial agents. Accordingly, this rejection should also be withdrawn.

Rejections Under 35 U.S.C. §103 and Statement of Common Ownership

Most of the rejections under 35 U.S.C. §103 are improper because they rely on patents that are only prior art under 35 U.S.C. §102(e). 35 U.S.C. §103(c)(1) provides that

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

As a result, U.S. Patent Nos. 6,579,469, 6,585,967, 6,602,496, 6,942,875, 2003/0082116, 2004/0223946, 2004/0151688, 6,455,064, 6,512,023, 6,605,667 and 6,746,667 are not properly cited in rejections under 35 U.S.C. §103 because they are only prior art under 35 U.S.C. §102(e) and were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made. It is further noted that U.S. Patent No. 6,767,552 is not properly citable as prior art under any section of the statute and does not qualify as prior art under 35 U.S.C. §102(e) because it is not a patent to "another" as it includes the same inventive entity as the present application. The remaining portions of each rejection are addressed below.²

Claim 6 is rejected under 35 U.S.C. §103(a) over WO '150, U.S. Patent Nos. 6,281,265, 6,310,166, 6,352,704 and 6,455,033 each in view of U.S. Patent No. 5,800,803 (Paragraph No. 25 of the Official Action). It would not have been obvious to one of ordinary skill in the art to combine any of the primary cyanoacrylate references with the '803 patent because the '803 patent is not directed to cyanoacrylates in view of the known problems in combining cyanoacrylate monomer with anti-microbial agents. Accordingly, the rejection should be withdrawn.

Claims 15 and 25 are rejected under 35 U.S.C. §103(a) over WO '150, U.S. Patent Nos. 6,281,265, 6,455,033 each in view of U.S. Patent No. 6,310,166 (Paragraph No. 26 of the Official Action). None of these references disclose the claimed combination including any of the listed anti-microbial agents. In view of the known problems in combining cyanoacrylate monomer with anti-microbial agents, it would not have been obvious to arrive at the presently claimed combination. Accordingly, the rejection is respectfully requested withdrawn.

² It is noted that many of the rejections suggest that it would have been "obvious to try" combining various anti-microbial agents with cyanoacrylate monomer. This is not a proper basis for obviousness.

Claim 27 is rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,579,469 in view of U.S. Patent No. 6,310,166 (Paragraph No. 27 of the Official Action). This rejection is improper because U.S. Patent No. 6,579,469 is not prior art. Accordingly, the rejection should be withdrawn.

Claims 4 and 20 are rejected under 35 U.S.C. §103(a) over WO '150 in view of WO '613 (Paragraph No. 28 of the Official Action). This rejection is moot because claims 4 and 20 are cancelled.

Claims 2-5, and 17-20 are rejected under 35 U.S.C. §103(a) over U.S. Patent Nos. 6,310,166, 6,352,704 and 6,455,033 each in view of WO '163 (Paragraph No. 29 of the Official Action). This rejection is also moot because claims 2-5 and 17-20 are cancelled.

Claims 13, 14, 23, and 24 are rejected under 35 U.S.C. §103(a) over U.S. Patent Nos. 6,281,265 and 6,455,033 each in view of U.S. Patent No. 6,666,870 (Paragraph No. 30 of the Official Action). Neither the '265 patent nor the '033 patent disclose the use of cyanoacrylate monomer. The '870 patent does not disclose the claimed anti-microbial agents. The '033 patent is directed to a method for making artificial nails. It would not have been obvious to combine the references as suggested because of the known problems associated with mixing cyanoacrylate monomer and anti-microbial agents. Moreover, the present claims are directed to monomeric adhesive compositions and one of ordinary skill in the art would not look to the artificial nail art in arriving at a stable cyanocrylate monomer including an anti-microbial. Accordingly, it is requested that the Examiner withdraw this rejection.

Claims 1-14, 16-24, and 28-29 are rejected under 35 U.S.C. §103(a) over U.S. Patent Nos. 5,981,621, 6,143,352, and 6,306,243 each in view of WO '613 and U.S. Patent No. 5,800,803 (Paragraph No. 31 of the Official Action). None of the primary references disclose the claimed antimicrobials. WO '613 also fails to disclose the claimed antimicrobials. The '803 patent does not disclose cyanoacrylates. It would not have been obvious to make the claimed combination because of the known problems in mixing cyanoacrylate monomer with anti-microbial agents. Accordingly, it is respectfully requested that the Examiner withdraw this rejections as well.

Claims 15 and 25-27 are rejected under 35 U.S.C. §103(a) over U.S. Patent Nos. 5,981,621, 6,143,352, and 6,306,243 in view of WO '613 or U.S. Patent No. 5,800,803 (Paragraph No. 32 of the Official Action).³ This rejection is also respectfully requested withdrawn for all of the same reasons as the previous rejection of Paragraph No. 31 of the Official Action.

³ It is noted that this rejection also makes reference to "US '116". It is unclear which patent is intended.

Conclusion

For the foregoing reasons, claims 1, 7-12, 15, 16, 20-22 and 25-29 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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